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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
05/06/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,714	DEBRUYNE ET AL.	
	Examiner	Art Unit	
	MICHAEL KAHELIN	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-82* is/are pending in the application.

4a) Of the above claim(s) *66-69 and 82* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-65 and 70-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/17/2010 has been entered.

Election/Restrictions

2. Newly submitted claim 66-69 and 82 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the originally claimed species do not relate to a single general inventive concept under PCT Rule 13.1. See the Office communication of 1/21/2009

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 66-69 and 82 are withdrawn from consideration as being directed to a non-elected invention.

3. Claims 66-69 and 82 are withdrawn from further consideration as being drawn to a nonelected species, there being no allowable generic or linking claim. A prospective election was made **without** traverse in the reply filed on 2/17/2010, confirming the previous election made 2/23/2009.

Claim Objections

4. Claims 66-69 and 82 objected to because of the following informalities: Applicant has indicated that these claims are withdrawn, based on the species election of 2/23/2009. However, the status identifiers do not indicate that the claims are withdrawn. Appropriate correction is required.

5. Claims 54 and 70 are objected to because of the following informalities: in claim 54, line 7, --that-- should be inserted between "such" and "the lead"; in claim 70, line 2, "having a one" should read "having one." Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 54-65 and 70-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramm et al. (US 6,936,040, hereinafter "Kramm") in view of Kuzma (US 6,309,410, hereinafter "Kuzma").

9. In regards to claims 54, 56, 70, and 72, Kramm discloses a stimulator unit configured to generate stimulation signals (col. 5, lines 37-39 and Fig. 2); an electrode assembly comprising a lead extending from the stimulator unit, and a contiguous elongate member implantable in the tortuous coronary vasculature (col. 2, lines 57-65); one or more electrodes disposed on or in the elongate member each configured to deliver electrical stimulation to the cochlea (or any other location in the body; col. 5, lines 6-16); and an annular collar slidably mounted around the lead such that the lead extends through a lumen in the collar (Fig. 6; element 48 and distal portions of 42 and 56), the collar having a chamber therein (distal portion of 56) configured to receive a biactive substance (col. 6, lines 45-50) and an outlet through which the bioactive substance can pass from the chamber to a target site in recipient (outlet of 56). Although Kramm discloses that the lead is dimensioned to be implantable in the small, tortuous coronary vasculature, Kramm does not explicitly disclose that the lead is implantable in a cochlea/middle ear, the collar dimensioned to slide along the lead in the middle ear, or that the system is a cochlear implant. However, Kuzma discloses a similar cochlear drug delivery/electrical stimulation system implantable in a cochlea middle ear, the drug delivery device dimensioned to slide along the lead in the middle ear (Figs. 2a and 2b) to provide the predictable results of providing known therapeutic auditory stimulation while providing known pharmacological benefits such as preventing

fibrosis or promoting neural growth (col. 3, lines 40-49). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kramm's device by providing a cochlear drug delivery/electrical stimulation system implantable in a cochlea middle ear, and the collar dimensioned to slide along the lead in the middle ear to provide the predictable results of therapeutic auditory stimulation while providing known pharmacological benefits such as preventing fibrosis or promoting neural growth.

10. In regards to claims 57 and 73, Kramm discloses that the collar has a plurality of different diameters along its length (Fig. 6).

11. In regards to claims 58 and 74, the resistance to flow provided by the semi-permeable distribution device (48) necessarily retains the bioactive substance in the chamber for some arbitrary period of time (col. 6, lines 45-50).

12. In regards to claims 60 and 75, the chamber is annular and surrounds the lumen of the collar (Fig. 6 -- in this case 48 is considered part of the "chamber" and/or 56 alone can be considered the chamber because it is annular and at least partially surrounds the lumen; the claims not require "completely surround[ing]" the lumen).

13. In regards to claims 61 and 76, the outlet is annular (Fig. 6).

14. In regards to claims 62-65 and 78-81, the collar comprises an inlet in fluid communication with the chamber (an arbitrary point on 56 proximal to 48 such that the outlet is on the "distal end" of the collar structure); the chamber (56) being configured to pass the bioactive substance from the inlet to outlet (Fig. 6); and wherein the chamber is a pipe extending through the collar from the inlet to outlet (Fig. 6).

15. In regards to claims 55, 59, 71, and 77, Kramm's modified invention discloses the essential features of the claimed invention except for a "stop" on the lead that prevents the substance delivery means from moving past the stop means; or an outlet that includes a semi-permeable membrane. However, Applicant admitted prior art teaches that it is well known in the cochlear stimulation arts to provide stops on leads that prevent positioning devices, such as Kramm's, from moving past the stop means to provide the predictable result of avoiding damage to the tissue and ensuring proper placement of the electrodes; and to provide drug outlets that include semi-permeable membranes to provide the predictable result of releasing drugs at a specifically desired rate. Therefore, it would have been obvious to one having ordinary skill at the time the invention was made to provide Kramm's invention with a stop on the lead that prevents the positioning device from moving past the stop means to provide the predictable result of avoiding damage to tissue from too deep of insertion and ensuring proper placement of the electrodes; and to provide a drug outlet that includes a semi-permeable membrane to provide the predictable result of releasing drugs at a specifically desired rate.

Response to Arguments

16. Applicant's arguments filed 2/17/2010 have been fully considered but they are not persuasive. Applicant argued that the Kramm's system cannot be fairly considered an "annular collar" because it is not a "ring." However, even the definition provided in "Remarks" of 2/17/2010 is not so limited -- the definition including "of, relating to, or forming a ring." Kramm's system is of/related to/forming a ring because it surrounds the

lead (*i.e.*, forms a ring around) along at least a portion of its length. Even if the entire catheter structure of Kramm's Figure 6 cannot be considered an annular collar (which the Examiner does not concede -- see below) nothing in the claim language precludes an interpretation of an arbitrary distal portion of elements 48, 56, and 42 being considered the "annular collar." Furthermore, although Applicant appears to be taking the position that a tube/catheter cannot be fairly interpreted to be an "annular collar" because these elements are not rings, the Examiner respectfully asserts that the claim language indicates that the "annual collar" is not so limited by use of the term "lumen." The ordinary meaning of lumen is the interior of a tube or vessel, and thus implicitly indicates that the scope of "annular collar" includes tubes or vessels. Under this reading, the entire catheter structure of Kramm can fairly be interpreted as an "annular collar." In other words, Applicant appears to be arguing that "rings" and "tubes" are mutually exclusive features, but the claim language refers to the asserted "ring" as having features unique to "tubes."

17. Based on Applicant's failure to traverse the taking of Official Notice in the Office Action of 11/17/2009, the Examiner is considering these features to be Applicant admitted prior art (claims 55, 59, 71, and 77). See MPEP § 2144.03(c).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762